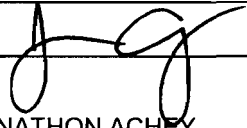



Doc Code: AP.PRE.REQ

PTO/SB/33 (07-09)

Approved for use through 07/31/2012. OMB 0651-0031  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
<p>I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on <u>September 21, 2011</u></p> <p>Signature <u></u></p> <p>Typed or printed name <u>JONATHON ACHEY</u></p>		Application Number	
		10/689,487	
		Filed	
		October 20, 2003	
First Named Inventor		Thomas W. Davison	
Art Unit		Examiner	
3775		Nicholas W. Woodall	
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a notice of appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five (5) pages may be provided.</p>			
<p>I am the</p> <p><input type="checkbox"/> applicant/inventor.</p> <p><input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> attorney or agent of record. Registration number <u>40,364</u></p> <p><input type="checkbox"/> attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____</p>		<p><u></u> Signature</p> <p>NANCY J. PARSONS Typed or printed name</p> <p>612.677.9050 Telephone number</p> <p><u>9/21/11</u> Date</p>	
<p>NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.</p>			
<p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**REASONS FOR PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicants submit that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a prima facie rejection.

Claims 18-23, 25, 26, and 46 are rejected as being unpatentable over Foley (US 5,792,044) in view of Ash (WO 83/03189) and Zdeblick (US 6,206,922). None of Foley, Ash, Zdeblick, or a combination thereof appears to teach or suggest the structure recited in independent claim 18. Additionally, the Examiner has not provided any rational reason for modifying the references to achieve the claimed structure. The rejection is thus an error. The Examiner acknowledges that Foley fails to disclose a system comprising an elongate body that is actuatable as claimed. Zdeblick also does not appear to teach an elongate body that is actuatable as recited in the claim. Ash is cited as teaching a device having an elongated body expandable at the distal end to provide viewing and operation room. The Examiner asserts that it would have been obvious to manufacture the device of Foley with an expandable distal end in view of Ash to provide viewing and operation room. The Examiner has not indicated, in the rejection itself, any reference that teaches or suggests a device as claimed in which the passage provides unobstructed access from the proximal end to the distal end when in the second configuration. The Examiner has also not provided any rational reason why one of ordinary skill in the art would have been motivated to modify Foley, Ash, and Zdeblick to achieve the claimed structure. Applicants submit that even if one were to combine Foley, Ash, and Zdeblick, one would not arrive at the system as claimed. The rejection is thus an error.

In the Advisory Action, the Examiner asserts that the test for obviousness is not whether the features of one reference may be bodily incorporated into the other to produce the claimed subject matter but simply what the combination of references makes obvious to one of ordinary skill in the art. The Examiner asserts that the test for obviousness is not how the actuation mechanism of Ash would fit into the Foley device, but rather that the teachings of Ash would make it obvious to provide the cannula of Foley having a first insertion configuration and a second expanded configuration. The Examiner appears to be asserting that Ash provides the motivation to make the fixed cannula of Foley actuatable at the distal end, but with some mechanism other than the internal actuation specifically taught by Ash. Applicants submit that even if one considered Ash to provide motivation for making the distal portion of Foley's device actuatable, the only mechanism provided by is the internal mechanism. The Examiner has not

provided any mechanism for actuating the device of Foley other than that taught by Ash. While bodily incorporation may not be necessary for obviousness, Applicants submit that some mechanism must be provided for the actuation of the Foley device that would not obstruct the passage. The Examiner appears to be asserting that Ash provides the idea of actuating the distal end of a tubular device such as that taught by Foley, and that this idea renders any mechanism of actuation obvious. Applicants respectfully disagree. While Ash can be seen to teach a device with an expandable distal end, the only means of actuating the distal end provided by the Examiner is the internal mechanism taught by Ash, thus the mechanism providing the actuation must be considered in any combination. If the Examiner is relying on Ash only for the idea of actuating the distal end of the Foley device, but the Examiner does not wish to rely on Ash for the internal actuation mechanism, Applicants submit some teaching of an actuation mechanism that would not obstruct the passage must be provided. The Examiner has not provided such a teaching or any rational reason why one of ordinary skill in the art would have been motivated to provide an actuation mechanism to the Foley device that did not partially obstruct the passage. The only indication of such a mechanism is found in Applicants' specification, which is improper. The rejection is thus an error.

The rejection appears to be made on the basis of combining the actuation feature of Ash with the fixation systems of Foley and Zdeblick, thus it appears the combined teachings must be addressed. Because Ash contains the only teaching of an actuated device, the actuation mechanism is the only means available for making the asserted combined device. The Examiner has not provided any other means of actuation. As can be seen in FIG. 2 of Ash, the actuation mechanism 32 is located within the tube 12, with the actuator 32 urging the levers 28 apart when the internal conduit 34 is moved relative to the external tube 12. The internal conduit 34 of Ash appears to provide an unobstructed passage but this conduit is not itself actuatable, as seen in FIGS. 1-2. The part of Ash that is actuatable is the levers 28 at the distal end of the external tube 12. However, the outer tube 12 cannot be seen to be a passage that provides unobstructed access from the proximal end to the distal end when in the second (expanded) configuration. As is clearly seen in FIG. 2, the actuator 32, internal conduit 34, and access channel 88 at least partially obstruct the passage defined by the inner surface of the outer tube 12. Thus, there does not appear to be any structure in Ash that can be considered to form a passage with an unobstructed access from the proximal end to the distal end when in the second (expanded)

configuration. The fact that Foley teaches a fixed cannula with an unobstructed passage does not provide a solution. If one were to combine the unobstructed passage cannula of Foley with the actuatable device of Ash, the internal actuation mechanism of Ash must be considered because no other actuation mechanism is taught or suggested by the combination of references, and the Examiner has not provided any rational reasoning for using the idea of a distal actuating portion from Ash but not using the internal actuation mechanism of Ash. The Examiner asserts that Applicants cannot argue on a piece-meal basis. While Applicants' arguments may appear to be piece-meal, Applicants are merely pointing out that none of the cited references appear to teach a claimed element, and the Examiner has not provided any additional reasoning for achieving the claimed element. Applicants have considered the combined teachings of Foley, Ash, and Zdeblick. However, as discussed above, Ash appears to provide the only actuation mechanism, which is clearly taught to be inside the outer tube. Because the only actuation mechanism is taught as being inside the tube, a combination of Ash, Foley, and Zdeblick would appear to have an internal actuation mechanism.

The Examiner appears to be asserting that because Ash teaches a device that can be actuated, and Foley teaches an unobstructed fixed cannula, that somehow, one could make the unobstructed cannula of Foley be actuated, but without using the internal actuation mechanism of Ash. The Examiner has not provided any teaching or suggestion of an alternative actuation mechanism that would actuate the cannula of Foley while allowing the cannula to remain unobstructed. Applicants do not believe the standard for obviousness renders all possible means of actuating part of a device obvious merely because a reference teaches one such means.

Further, Applicants note that the claimed passage is defined by the inner surface of the elongate body, and it is the cross-sectional area of the passage in the second configuration that is greater at a first location distal to a second location. If one considers the tube 12 of Ash to be the elongate body, then the inner surface defines the passage, which, as clearly seen in FIG. 2, is obstructed by the actuator 32, the internal conduit 34, and the access channel 88. The Examiner asserts that these elements "are not part of the passage, but are placed within the passage which gives these structures and elements unobstructed access from the proximal end of the elongate member to the distal end of the elongate member in the second configuration as shown clearly in Figure 2." Applicants respectfully disagree. Ash teaches the actuator means 32 and internal

conduit 34 as being part of the device and connected to the tube 12, in order to provide the actuation of the levers 28. Ash specifically teaches:

As shown in the embodiment of FIGURES 1-3 the actuator means 32 includes a mechanical linkage 46 mechanically interconnecting the internal conduit 34 and the levers 28. As the internal conduit 34 is moved proximally with respect to the external tube 12, the mechanical linkage 46 extends outwardly to urge the distal ends 44 levers 28 apart.

See page 7, lines 8-14 and FIGS. 1-3. Ash clearly teaches the actuator means 32 and internal conduit 34 as part of the device, disposed within the tube 12 as seen in the figures. One of ordinary skill in the art would understand from the teachings of Ash that the actuator means 32 and internal conduit 34 is not inserted into the tube 12 but is instead part of the tube structure. The Examiner asserts that “[i]f the device of Ash did not have an unobstructed passage from the proximal end to the distal end of the elongate member, then those structures and elements would not be able to perform any functions on the patient.” Applicants acknowledge that Ash appears to provide an unobstructed passage in the form of the internal conduit 34, but conduit 34 is not actuatable. Ash appears to teach an obstructed passage defined by the inner surface of actuatable tube 12, and an unobstructed but non-actuatable passage defined by the internal conduit 34. Ash thus cannot be seen to teach the claimed elements.

Regardless of which parts of Ash are considered the elongate body, the structure of Ash cannot be seen to provide an unobstructed passage as claimed. While the rejection is based on the combination of Foley, Ash, and Zdeblick, none of the references appears to provide a teaching or suggestion of the claimed structure. Further, the Examiner has not provided a rational reason for one of ordinary skill in the art to modify the combined references to achieve the structure as claimed. The rejection is thus an error.

It is submitted that, in light of the above remarks, all pending claims are now in condition for allowance. If a telephone interview would be of assistance, please contact the undersigned attorney at (612) 677-9050.